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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,192	09/25/2006	Mette Gronborg	50721/006002	5685

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EXAMINER	
HAYES, ROBERT CLINTON	

ART UNIT	PAPER NUMBER
1649	

NOTIFICATION DATE	DELIVERY MODE
03/06/2012	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

Office Action Summary	Application No.	Applicant(s)	
	10/594,192	GRONBORG ET AL.	
	Examiner	Art Unit	
	ROBERT C. HAYES	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 December 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *92,129 and 132-136* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *92,129 and 132-136* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/9/12*
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/15/11 has been entered.

2. The rejection of claims 132 & 133 under 35 U.S.C. 112, first paragraph, for lack of written description is withdrawn due to Applicants' amendment of the claims.

3. The rejection of claims 92, 129 & 132-133 under 35 U.S.C. 112, first paragraph, for lack of enablement is withdrawn due to Applicants' amendment of the claims.

4. The rejection of claims 132-133 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn due to Applicants' explanation on pages 11-12 of the response.

It is suggested that claim 132 be amended to recite "and further comprising [-having] all amino acids marked…", and claims 134 & 135 be amended to recite "SEQ ID NO: 4 [; wherein the polypeptide comprises] and which further comprises the amino acid sequence of SEQ ID NO: 60".

5. The rejection of claims 92, 129 & 132-133 under 35 U.S.C. 102(b) as being anticipated by Tang et al/ HYSEQ, INC (WO 01/57190; IDS Ref # B6) is withdrawn due to the amendment of the claims to recite "administering *to the striatum* of a subject".

6. Applicant's arguments filed 11/23/11 and 12/15/11 have been fully considered but they are not deemed to be persuasive.

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claim 92 stands rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons made of record in Paper NOs: 20090618, 20101001 & 20110815, and as follows. **This is a written description rejection**.

Applicants argue on pages 7-10 of the response what amino acids are not to be mutated (i.e., conserved) to meet the limitation of "at least 95% identity...". Although claims 129, 132-133, and new claims 134-136 do recite such, base claim 95 does not recite what critical amino acid residues must be present in order to reasonably show a correlation between structure and function. Therefore, base claim 92 remains rejected for the reasons previously made of record; analogous to the situation decided in Fiers v. Revel, and Univ. California v. Eli Lilly and Co.

9. New claim 136 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection**.

No proper antecedent basis nor conception in context with that described within the specification at the time of filing the instant application is apparent in "Example 15" for the recitation of "capable of protecting striatal neurons against degeneration"; thereby, constituting new matter.

Applicants are invited to indicate by page and line number where such claim language is properly contemplated.

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 92, 129, 132-133 & 134-136 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tang et al/ HYSEQ, INC (WO 01/57190; IDS Ref # B6), for similar reasons made of record in Paper NOs: 20090618, 20110318 & 20110815, and as follows.

Tang et al teach administering the polypeptide of SEQ ID NO: 1401, which is 100% identical to SEQ ID NO: 4 of the instant invention (e.g., see pages 4-5, 28-29 & 65-66), to treat nervous system disorders (section 4.10.17; pages 60-61), in which page 61 (line 3) specifically lists treating Huntington's chorea (i.e., as it relates to claim 92 & 94). The only active step is the administration of the polypeptide identical to SEQ ID NO: 4 to Huntington's patients. Whether other polypeptides are described by Tang is immaterial because Tang still teaches use of the polypeptide identical to SEQ ID NO: 4 to treat Huntington's patients. However, although Tang do teach local administration (e.g. pg. 66; as it relates to directly administering into the brain), Tang et al do not specifically disclose administration "to the striatum".

It would have been obvious to one of ordinary skill within the art to administer Tang's polypeptide of SEQ ID NO: 1401 into the striatum of a Huntington's patient because this is the local brain region affected in Huntington's disease.

It is noted that although Tang does teach numerous polypeptides to be administered to treat numerous disease states, administration of Tang's polypeptides to Huntington patients is

readily suggested by Tang, which therefore, is obvious to try based upon the specific suggestions of Tang.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker, can be reached on (571) 272-0911. The fax phone number for this Group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Robert C. Hayes/, Ph.D.
Primary Examiner, Art Unit 1649
February 29, 2012